UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

TRUE HEALTH DIAGNOSTICS, LLC, Plaintiff, vs. ALEX M. AZAR II, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and SEEMA VERMA, ADMINISTRATOR FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES Defendants.	§ § § § § § § § § § § § §	CIVIL ACTION NO. 9:19-cv-110 **FILED UNDER SEAL**

DEFENDANTS' MOTION TO DISMISS AND COMBINED RESPONSE TO PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER AND MOTION TO SEAL CASE

Defendants file this Motion to Dismiss and Combined Response respectfully requesting the Court to dismiss this action filed by True Health Diagnostics, LLC ("True Health or THD") for lack of subject matter jurisdiction and failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(1) and 12(b)(6).[1] Defendants also request that this action be unsealed as True Health has provided no legitimate basis for overriding "the vital public interest

[1] The Defendants do not have sufficient information to confirm whether Plaintiff has satisfied the requirements for service on the United States, its agencies, corporations, officers, or employees as set forth in Rule 4(i) in the Federal Rules of Civil Procedure. A plaintiff must strictly comply with Rule 4 regardless of whether the United States has actual knowledge of the suit. *See McMasters v. United States*, 260 F.3d 814, 817 (7th Cir. 2001) ("[N]othing in the Federal Rules of Civil Procedure allows a judge to excuse service altogether. Actual notice to the defendant is insufficient; the plaintiff must comply with the directives of Rule 4.") There is no personal jurisdiction over the Defendants if they have not been properly served. *See Campbell v. United States*, No. 4:11-cv-711, 2012 WL 830508, at *2 n.1 (E.D. Tex. Feb. 3, 2012) (Mazzant, J.) ("Plaintiff failed to effect proper service on the United States under Rule 4(i) because he did not serve the United States attorney or the United States attorney general, and he must serve both …. Thus, there is no personal jurisdiction over the United States."). Because Defendants have not been able to confirm whether Plaintiff complied with the service requirements set forth in Rule 4 prior to the filing deadline established by the Court, Defendants also move to dismiss pursuant to Rule 12(b)(5) due to insufficient service of process and Rule 12(b)(2) due to lack of personal jurisdiction.

in open judicial proceedings." 28 C.F.R. § 50.9. Finally, if the action is not dismissed, Defendants ask that the action be transferred to the Sherman Division, where a related case has been pending *for over two years*.

INTRODUCTION AND FACTUAL BACKGROUND

If there is one thing "true" about True Health during its relatively short existence, it is this: True Health operates as if the rules do not apply to it. Consider, as examples:[2]

1. In 2015, after purchasing the assets from another laboratory company called Health Diagnostic Laboratory, Inc. ("HDL"), driven out of business because of pervasive healthcare fraud, True Health hired many of the individuals associated with those prior fraud schemes and began perpetrating its own fraud schemes against Medicare. [Decl. at ¶4].

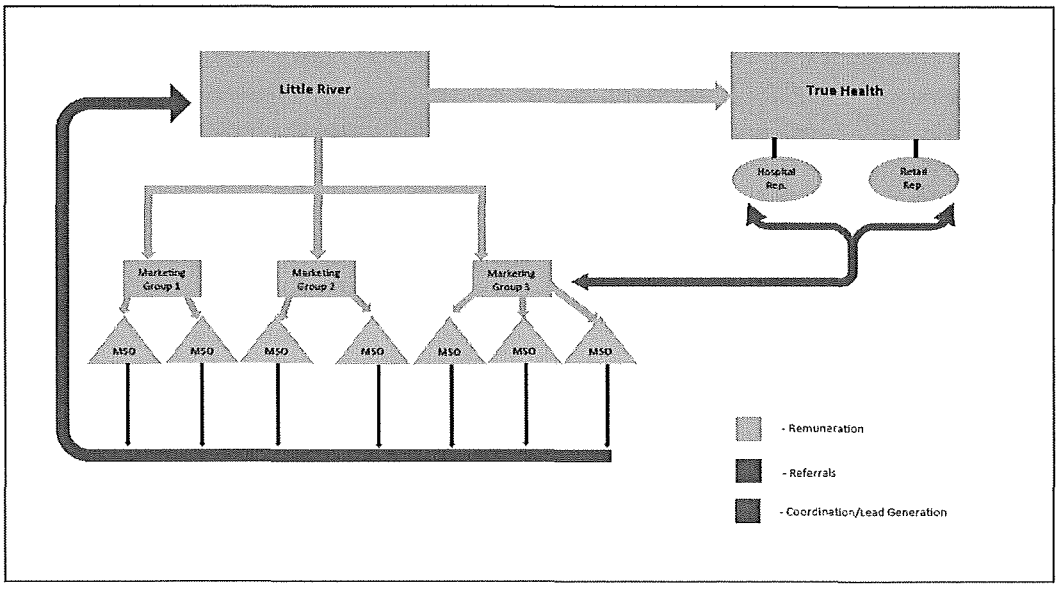
2. True Health began coordinating with rural hospitals and recruiters to route patient blood samples through rural hospitals to take advantage of a higher rate of reimbursement by Medicare. [Decl. at ¶6]. True Health had provided many physician offices referring to True Health with an embedded True Health-employed phlebotomist that worked in the physician's office. [Decl. at ¶7]. Once True Health conspired with a particular rural hospital, the True Health employee would become an "employee" of the rural hospital (if only on paper), and patient samples would then be steered to the rural hospitals rather than directly to True Health. [Decl. at ¶7].

3. To induce physicians to order laboratory tests from small rural hospitals, True Health coordinated with marketing groups to enlist its existing physician customers into so-

[2] The Department of Justice continues to investigate the extent of the fraud perpetrated by True Health, including just how many physicians and other individuals and entities were involved in the Anti-Kickback Statute violations. The United States provides limited background of the facts, in light of its ongoing civil and criminal investigations. As True Health recognizes, payment suspensions like the one at issue here can be extended if the Department of Justice requests extension based on "an ongoing investigation and the anticipated filing of a criminal and/or civil action." Compl. (Doc. #2) at ¶29; 42 C.F.R. § 405.371(b)(3)(ii).

called "Management Services Organizations," often referred to as "MSOs." [Decl. at ¶¶8-9]. Physicians were then grouped with other physicians of similar referral volumes and compensated for referrals sent to hospitals associated with True Health. [Decl. at ¶10]. These physician payments were intended to be disguised—albeit not well—as returns on "investments" in the MSOs. If the payments were truly investment dividends (they were not), many of the referring physicians received a rate of return of thousands of percentages over the initial "investment." [Decl. at ¶11]. For instance, one physician "invested" $3,000, but, within a few years, was paid over $308,000—representing a "return on investment" exceeding 10,000%. [Decl. at ¶11].

4. True Health reaped ill-gotten profits from these arrangements by setting up and running the laboratories at the hospitals and/or by obtaining various management fees from the rural community hospitals. [Decl. at ¶12]. In large part due to True Health's parasitic exploitation of one such hospital named Little River Healthcare—located in a small rural community in Central Texas—the hospital was left in financial ruin and forced to file bankruptcy. [Decl. at ¶14]. A graphical representation of the scheme is as follows:



[Decl. at ¶13].

5. True Health's executives knew these arrangements were abusive. In February 2016, one of True Health's Senior Vice Presidents wrote to, among others, True Health's CEO stating that these types of arrangements were "a powder keg waiting to explode on us." [Decl. at ¶17]. By way of further example, in May 2016, the same Senior Vice President wrote to another True Health official that law enforcement was asking about MSOs and money to referring doctors. He acknowledged that "the pain for alot [sic] of people is coming soon. . . . I think this is all gonna [sic] make hdl [sic] look like child's play. [P]eople are gonna [sic] go to prison[.]" [Decl. at ¶18].

6. In late 2016, Medicare investigators visited True Health's headquarters, requested documents, placed a number of True Health's top-referring physicians on prepayment review, and initiated a billing audit. [Decl. at ¶29]. Then, in January 2017, True Health executed a recapitalization transaction in which it took on $110 million of debt while turning around to pay its executives and other shareholders approximately **$130 million in distributions**. [Decl. at ¶29]. True Health's CEO received over $36 million. [Decl. at ¶29]. Other executives, including Chief Financial Officer Christian Richards, received millions of dollars. [Decl. at ¶29]. True Health neglected to inform the Court of this information when blaming Defendants for True Health's financial strain.[3]

7. Nor did True Health inform the Court that True Health has represented to the United States on multiple occasions that it would be forced to file bankruptcy due to a lack of funds after a certain date. On every prior such occasion, the date came and went and True Health kept operating, including hiring more attorneys. [Decl. at ¶¶21 - 27].

[3] This background of True Health's business practices and abuses puts into stark relief just how unsympathetic True Health's arguments are about its allegedly dire financial situation. Defendants are appropriately protecting the public fisc and taxpayer funds as the investigation of the full extent of True Health's fraud proceeds.

8. In addition, in the second half of 2018, True Health insisted that the United States should agree to work quickly toward settling the pending *qui tam* False Claims Act investigation. The United States responded that it was not prepared to do so as its investigation was ongoing. True Health did not relent, and the United States agreed to explore a potential resolution related to, among other things, the Little River scheme above. True Health ultimately offered over $26 million as settlement, which included payment of over $18 million held in escrow. The United States agreed to work with True Health toward a civil settlement based on True Health's limited ability to pay, notwithstanding the fact that estimates place True Health's liability to the United States in excess of $100 million under the False Claims Act.

9. Yet, True Health did not disclose these background facts to the Court and now argues that Defendants have used the suspended funds "as leverage against True Health to seek to unreasonably extract not one, but two settlements based on meritless allegations without any basis in fact." Compl. (Doc. #2) at ¶91. This is demonstrably false. CMS issued two suspensions based on two separate sets of claim submissions. Contrary to THD's representations, the claims included as examples in the 2019 suspension were submitted by THD after imposition of the first suspension and were not among the bases for the first suspension.

10. Nor did True Health properly inform the Court pursuant to Local Rule CV-42(a), entitled "Duty to Notify Court of Collateral Proceedings and Re-filed Cases," that a civil *qui tam* action against True Health has been pending in the Sherman Division for over two years. *See* Civil Action No. 4:16-CV-547. In fact, True Health filed this action in the Lufkin Division *after* counsel for the United States informed True Health's counsel that the *qui tam* is pending in the Sherman Division.[4] True Health apparently did not even bother to include that fact on the Civil

[4] In fact, True Health is headquartered in the Sherman Division. True Health appears to be unapologetically forum shopping in this action.

Cover Sheet initiating this matter. The following is a screen capture of the relevant portion of that filing showing no related case identified:

VI. CAUSE OF ACTION	Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*: 42 U.S.C. § 301; 42 U.S.C. § 1395	
	Brief description of cause: Action to enjoin CMS from unlawfully withholding Medicare reimbursements	
VII. REQUESTED IN COMPLAINT:	☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.	DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☐ Yes ☒ No
VIII. RELATED CASE(S) IF ANY	*(See instructions)*: JUDGE	DOCKET NUMBER
DATE 07/02/2019	SIGNATURE OF ATTORNEY OF RECORD /s/ J. Thad Heartfield	
FOR OFFICE USE ONLY		
RECEIPT # AMOUNT	APPLYING IFP JUDGE	MAG. JUDGE

11. True Health claims that this Court has subject matter jurisdiction over this action. Compl. (Doc. #2) at ¶16. It does not. Notably, True Health failed to distinguish, let alone cite, significant authority—including authority from this District—which holds that courts lack subject matter jurisdiction to entertain these types of actions. *See Texas Med. Enterprises, Inc. v. Sebelius*, No. 9:13CV27, 2013 WL 3215760 (E.D. Tex. June 24, 2013) (Clark, J.) (adopting Report and Recommendation holding Medicare overpayment dispute dismissal appropriate for lack of subject matter jurisdiction); *Lynncore Medgroup, Inc. v. Sebelius*, No. 4:11-CV-195, 2011 WL 6131953 (E.D. Tex. Dec. 7, 2011) (adopting Report and Recommendation holding complaint regarding Medicare suspension dispute—including request for mandamus, violations of the APA, request for injunctive and declaratory relief—should be dismissed for lack of subject matter jurisdiction); *see also Arthritis Treatment of Texas, PLLC v. Azar*, No. 3:16-CV-3470-S, 2018 WL 6592664 (N.D. Tex. Dec. 14, 2018) (dismissing Medicare overpayment dispute for lack of subject matter jurisdiction); *Timberlawn Mental Health Sys. v. Burwell*, No. 3:15-CV-2556-M, 2015 WL 4868842 (N.D. Tex. Aug. 13, 2015) (denying motion for TRO because court lacked subject matter jurisdiction); *Cyprian, Inc. v. Sebelius*, No. 4:10-CV-682-A, 2010 WL 11619492, at *2 (N.D. Tex. Oct. 25, 2010) (dismissing Medicare suspension dispute for lack of subject matter jurisdiction and explaining that only after the intermediary issues an overpayment

determination and plaintiff appeals that determination through each stage of the administrative process can plaintiff bring its claims to court); *Indeplus Grp. of Companies, Inc. v. Sebelius*, No. CIVA 3:10-CV-0557-O, 2010 WL 1372488, at *3 (N.D. Tex. Apr. 7, 2010) (dismissing Medicare suspension dispute for lack of subject matter jurisdiction and stating that the Court is "without the power to intervene in the agency's internal process for such disputes").

I. SUMMARY OF ARGUMENT

True Health's operations began in 2015 after it acquired the assets from HDL, a laboratory company which had been driven into bankruptcy largely because of pervasive Medicare fraud. True Health hired many of the individuals associated with HDL's prior frauds. In fact, in an internal True Health Board of Directors meeting on October 15, 2015, True Health noted that it was "'Business as usual'" after the HDL asset acquisition. [Decl. at ¶4].

True Health participates in the Medicare program as a supplier of diagnostic services. On May 26, 2017, the Centers for Medicare & Medicaid Services (CMS) suspended Plaintiff's Medicare payments under 42 C.F.R. § 405.371(a)(2) when it received credible allegations of fraud. [Exhibit A]. Those allegations were that between November 2015 and June 2016, True Health submitted claims for services: (1) ordered after a provider's date of death; (2) after a provider's Medicare billing privileges were deactivated; (3) when the referring providers had no prior or post history with the beneficiary whom the test was ordered for; and that failed to meet Medicare guidelines. *Id.* The Secretary issued its overpayment determination related to the first payment suspension on July 5, 2019.[5]

On June 13, 2019, CMS again suspended payments to Plaintiff after receiving additional credible allegations of fraud for claims submitted between June and September 2017. [Exhibit B]. That suspension was "based on, but not limited to, information that you misrepresented

[5] The Secretary issued two overpayment determination notices identifying a total overpayment of $27,467,142.32.

services billed to the Medicare program. More particularly, medical review of the claims submitted by True Health showed that these claims failed to meet Medicare guidelines because the claims were for services that were not medically necessary." *Id.*

CMS notified True Health on June 13, 2019 that it had "the right to submit a rebuttal statement" and any pertinent evidence, and that CMS would "determine whether the suspension should be removed, modified, or should remain in effect within 15 days of receipt of the complete rebuttal package." *Id.* CMS also committed to "notify [True Health] in writing of our determination to continue or remove the suspension and provide specific findings on the conditions upon which the suspension may be continued or removed, as well as an explanatory statement of the determination." *Id.*; *see* 42 C.F.R. § 405.375(b)(2). True Health submitted a rebuttal statement on June 25, 2019, but requested a temporary restraining order one week later without awaiting the determination, specific findings, and explanatory statement from CMS. True Health's request for a temporary restraining order is an attempt to prevent the Secretary from following his lawful procedures for temporarily withholding Medicare payments while the Medicare program investigates suspected incorrect claims submitted by True Health for payment. Since Congress entrusts the Secretary with the responsibility of administering the Medicare program, the Secretary is duty-bound to ensure the fiscal integrity of the Medicare Trust Fund. Accordingly, the Secretary is opposed to True Health's attempts to circumvent the requirements of the Medicare Act and the orderly administration of the Medicare program.

As set out more fully below, True Health's request for injunctive relief should be dismissed because it is barred by sovereign immunity and because True Health has failed to present and channel its claims through the administrative process created by the Medicare statutes as a prerequisite for seeking judicial review of this matter. Moreover, the suspension of

payments is not a final agency determination and is therefore not yet subject to judicial review under 42 U.S.C. § 405(g). Additionally, this Court does not have subject matter jurisdiction under 28 U.S.C. § 1331 and 1361; 42 U.S.C. § 405(g); the All Writs Act, 28 U.S.C. § 1651(a); *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*, 403 U.S. 388 (1971); the Court's inherent equity powers; or the Court's power to preserve its own jurisdiction. Accordingly, this action should be dismissed.

II. STATUTORY AND REGULATORY BACKGROUND

Medicare is a pay-first system. Medicare suppliers submit claims for payment by electronic billing without any records, documents, or proof that the services were provided or that the services meet Medicare requirements. Medicare's computer systems pay those claims automatically—typically within a couple of weeks after submission. So, when CMS suspects that a supplier is submitting fraudulent claims, federal regulations allow CMS to temporary withhold Medicare payments until it can determine if the supplier is submitting proper claims. 42 C.F.R. § 405.370 - 405.372. Under those regulations, Medicare payments may be, "[i]n cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the Office of Inspector General (OIG), and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments." 42 C.F.R. § 405.371(a)(2). "A credible allegation of fraud is an allegation from any source, including but not limited to the following: (1) Fraud hotline complaints[,] (2) Claims data mining[,] (3) Patterns identified through provider audits, **civil false claims cases, and law enforcement investigations**." 42 C.F.R. § 405.370(a) (emphasis added). "Allegations are considered to be credible when they have indicia of reliability." *Id.*

At the end of every 180 day-period after CMS imposes a payment suspension based on fraud, CMS evaluates whether there is good cause to not continue the suspension and requests a certification from the OIG or other law enforcement agency that the matter is still under investigation and warrants continuation of the suspension. 42 C.F.R. § 405.371(b)(2). After 18 months, CMS must deem that good cause to end the suspension exists unless the matter is being considered by the OIG for administrative action or the Department of Justice requests that the suspension continue. 42 C.F.R. § 405.371(b)(3)(ii).

During the suspension period, the Medicare administrative contractor processes all claims received and the allowable amounts are credited to the provider's account. However, these allowable amounts are set aside, as if in escrow, until the investigation is completed. At the close of the investigation, "[p]ayments suspended under the authority of § 405.371(a) are first applied to reduce or eliminate any overpayments determined by the Medicare contractor, or CMS, including any interest assessed under the provisions of § 405.378, and then applied to reduce any other obligation to CMS or to HHS." 42 C.F.R. § 405.372(e). "In the absence of a legal requirement that the excess be paid to another entity, the excess is released to the provider or supplier." *Id.*

The provider is entitled to administrative and judicial review when there is an overpayment determination. In this regard, the Secretary has promulgated regulations setting forth an extensive statutory and administrative system of appeals available to parties that are dissatisfied with certain determinations by CMS or its contractor. 42 U.S.C. § 1395ff; 42 C.F.R. Part 405, Subpart I. Once an initial determination is made on a claim (*e.g.*, the denial of a claim), a beneficiary or a provider has the right to appeal Medicare coverage and payment decisions. The five levels of appeal are:

1) A redetermination of the initial claim decision (42 C.F.R. § 405.940 *et seq.*);
2) A reconsideration conducted by a Qualified Independent Contractor (QIC) (42 C.F.R. § 405.960 *et seq.*);
3) A hearing before an Administrative Law Judge (ALJ) (42 C.F.R. §§ 405.1002(a)(2), 405.1006(b));
4) Review by the Medicare Appeals Council (MAC) (42 C.F.R. § 405.1102(a)); and
5) Judicial review in a U.S. District Court ((42 U.S.C. § 1395ff(b)(1)(A)); 42 C.F.R. § 405.1136; 42 C.F.R. § 405.1130).

III. ARGUMENT

A. Subject-matter jurisdiction is lacking.

"Federal courts are courts of limited jurisdiction, and absent jurisdiction conferred by statute, lack the power to adjudicate claims." *Stockman v. Fed. Election Comm'n*, 138 F.3d 144, 151 (5th Cir. 1998). "The burden of proof for a Rule 12(b)(1) motion to dismiss is on the party asserting jurisdiction. Accordingly, the plaintiff constantly bears the burden of proof that jurisdiction does in fact exist." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001) (citations omitted). "When a Rule 12(b)(1) motion is filed in conjunction with other Rule 12 motions, the court should consider the Rule 12(b)(1) jurisdictional attack before addressing any attack on the merits." *Id.*

True Health predicates jurisdiction for its claims against Defendants on a number of alternate grounds: 28 U.S.C. § 1331 (federal question jurisdiction); 28 U.S.C. § 1361 (mandamus jurisdiction); 5 U.S.C. § 551 *et seq.* (the Administrative Procedure Act); and 42 U.S.C. § 405(g), 28 U.S.C. § 1651(a) (the All Writs Act), *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*, 403 U.S. 388 (1971); the Court's inherent equity powers; and the Court's power to

preserve its own jurisdiction. (Doc. 1, ¶ 17.) As explained below, none of these grounds support jurisdiction.

1. No federal question jurisdiction exists.

"The Medicare Act severely restricts the authority of federal courts by requiring 'virtually all legal attacks' under the Act be brought through the agency." *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 653 (5th Cir. 2012) (quoting *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000)). "By statute, claims under Medicare must first be presented to the HHS Secretary." *Id.* In establishing this procedure for the review of Medicare-related claims, Congress incorporated the following provision of the Social Security Act into the Medicare Act:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h) (made applicable to Medicare by 42 U.S.C. § 1395ii, with references to the Commissioner of Social Security considered to be references to the Secretary of Health and Human Services). Under the terms of section 405, judicial review of claims arising under the Medicare Act is available only after a "final decision" of the Secretary, in the manner provided in section 405(g). *See* 42 U.S.C. § 405(g); *Physician Hosps.*, 691 F.3d at 653 ("In summary, judicial review of such a claim [arising under Medicare] is available only after a party first presents the claim to the Secretary and receives a final decision."). But section 405 is also "more than a codified requirement of administrative exhaustion." *Physician Hosps.*, 691 F.3d at 654 (quoting *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975)). That is because the language of section

405(h) "is sweeping and direct and . . . states that no action shall be brought under § 1331, not merely that only those actions shall be brought in which administrative remedies have been exhausted." *Id.* (quoting *Weinberger*, 422 U.S. at 757).

No federal question jurisdiction exists for True Health's claims because section 405(h) precludes such jurisdiction over all claims arising under the Medicare Act. *See* 42 U.S.C. § 405(h) (providing that "[n]o action . . . shall be brought under section 1331"); *Shalala*, 529 U.S. at 5. "A claim arises under the Medicare Act if 'both the standing and the substantive basis for the presentation' of the claim is the Medicare Act, or if the claim is 'inextricably intertwined' with a claim for Medicare benefits." *RenCare, Ltd. v. Humana Health Plan of Tex., Inc.*, 395 F.3d 555, 557 (5th Cir. 2004) (quoting *Heckler v. Ringer*, 466 U.S. 602, 606, 623 (1984)) (internal citations omitted). The term "arising under" is broadly construed to encompass all claims for relief, regardless of whether the claimant seeks benefits, or declaratory or injunctive relief. *Ringer*, 466 U.S. at 615.

In this case, True Health seeks through a variety of claims and causes of action to overturn or reduce the suspension of its Medicare billing privileges. These claims are premised on the Medicare Act and on True Health's claimed entitlement to be an authorized Medicare supplier, and thus the claims "arise under" the Medicare Act, regardless of precisely how they are couched or presented. *See id.*; *Shalala*, 529 U.S. at 13–14; *see also Griego v. Leavitt*, No. CIV.A. 3:07-CV-1708-, 2008 WL 2200052, at *4, 6 (N.D. Tex. May 16, 2008) (explaining that both constitutional and statutory challenges to HHS's Medicare-related decisions arise under the Medicare Act and thus implicate section 405(h) and (g)). Because True Health's standing and the substantive bases for all of these claims arise under the Medicare Act, the claims are barred by § 405(h), no matter how they are styled. *See Shalala*, 529 U.S. at 10 (§ 405(h) "plainly bars §

1331 review . . . irrespective of whether the individual challenges the agency's denial on evidentiary, rule-related, statutory, constitutional, or other legal grounds"); *Heckler*, 466 U.S. at 615–16, 622 (APA claims and claims for injunctive and declaratory relief arose under the Medicare Act and were thus barred by § 405(h)); *Weinberger*, 422 U.S. at 760–61 (just because a plaintiff's claim may arise under the Constitution and the Social Security Act does not allow plaintiff to make an end run around § 405(h)); *Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 285–86 (5th Cir. 1999) (constitutional claim was "inextricably intertwined" with claim for administrative entitlement under the Medicare Act). Accordingly, under the plain language of section 405(h), no section 1331 jurisdiction exists.

Nor is True Health's heavy reliance on *Family Rehab., Inc. v. Azar*, 886 F.3d 496 (5th Cir. 2018), availing. There, the Fifth Circuit found jurisdiction over Family Rehab's procedural due-process and *ultra vires* claims as purely collateral to the underlying recoupment dispute—that is, the court held that Family Rehab's request for a hearing before its Medicare revenues were recouped was collateral to the underlying substantive dispute regarding the Medicare regulations. *Id.* at 503. Family Rehab had completed multiple administrative steps, requested an ALJ hearing, but did not receive an administrative hearing within 90 days. *Id.* at 500. The gravamen of the court's holding, then, was that the district court had jurisdiction to determine whether Family Rehab was entitled to the ALJ hearing before recoupment. Those issues are not before the Court in this case. First, *Family Rehab* involved recoupment, not suspension. Second, True Health has not completed any of the administrative steps at issue in *Family Rehab*. In fact, all due process will be available when CMS makes an overpayment determination and/or when True Health's False Claim Act case is litigated and tried.

2. No mandamus jurisdiction exists.

True Health next asserts that there is jurisdiction under the mandamus statute, 28 U.S.C. § 1361. This statute provides that "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. Mandamus is a drastic remedy, **reserved only for "extraordinary circumstances."** *Kerr v. U.S. Dist. Court for N. Dist. of California*, 426 U.S. 394, 403 (1976) (emphasis added).

"Before mandamus is proper, three elements must generally co-exist. A plaintiff must show a clear right to the relief sought, a clear duty by the defendant to do the particular act, and that no other adequate remedy is available." *Green v. Heckler*, 742 F.2d 237, 241 (5th Cir. 1984) (citations omitted). Mandamus is proper "only when the plaintiff's claim is clear and certain, and the duty of the officer is ministerial and so plainly prescribed as to be free from doubt." *Giddings v. Chandler*, 979 F.2d 1104, 1108 (5th Cir. 1992) (citation and internal quotes omitted). Mandamus "is not available to review the discretionary acts of [agency] officials." *Giddings*, 979 F.2d at 1108 (citations omitted). And, mandamus jurisdiction does not exist for other types of relief, such as an injunction or declaratory judgment, and is not appropriate when "a judicial decision favorable to the plaintiff would affect the merits of whether the plaintiff is entitled to the benefits" or when a plaintiff seeks a redetermination of an administrative decision. *See Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 764, 766–767 (5th Cir. 2011), 635 F.3d at 764, 766-767.

True Health has failed establish any of the elements of mandamus. True Health asserts that it "has meritorious challenges to the actions taken by federal officials in this case, and will vigorously assert its arguments during the administrative process that has already been initiated." Compl. (Doc. #2) at ¶104. However, other than its conclusory statement, True Health has

presented nothing to support its mandamus claim. True Health has not cited to any statute, regulation, or order that creates a clear right to relief and the Secretary's non-discretionary, purely ministerial duty to "(i) terminate their unlawful suspensions of Medicare payments to True Health until such time as an overpayment decision is issued and due process provided; (ii) immediately release the suspended funds being held in escrow by Defendants; and (iii) implement a full, speedy, and adequate administrative review process if Defendants intend to recoup or withhold any of True Health's Medicare payments in the future." *See id.* at ¶107. Indeed, whether to impose a payment suspension, how long to continue that suspension, and the percentage of payment to suspend are all discretionary decisions. *See* 42 C.F.R. § 405.371. And the relief that True Health seeks is clearly injunctive in nature. As such, mandamus jurisdiction is not available.

3. No APA jurisdiction exists.

True Health argues that the Administrative Procedure Act (APA) confers jurisdiction because "Defendants' unlawful suspensions of Medicare payments are arbitrary and capricious and contrary to law." Compl. (Doc. #2) at ¶97. However, the APA does not confer independent jurisdiction on district courts. *See, e.g.*, *Hamilton v. Gonzales*, 485 F.3d 564, 568–569 (10th Cir. 2007); *Fostvedt v. United States*, 978 F.2d 1201, 1203 (10th Cir. 1992) (APA "does not create an independent grant of jurisdiction for the review of agency actions"). Rather, the Supreme Court has held that a party seeking APA review in federal court must identify a jurisdictional grant from either the enabling statute or one of the general jurisdiction provisions under Title 28 of the United States Code. *Califano v. Sanders*, 430 U.S. 99 (1977). In *Califano*, the Supreme Court held that the APA did not itself constitute an implied grant of subject-matter jurisdiction permitting federal judicial review of the actions of the Secretary under the Social Security Act. *Id.* at 107. Thus, the APA does not create jurisdiction over this case.

4. No jurisdiction under the All Writs Act exists.

Similarly, True Health contends that the Court may issue injunctive relief against the Defendants under the All Writs Act (28 U.S.C. §1651(a)). It is well-settled, however, that "the Act itself is not a grant of jurisdiction." *In re Tennant*, 359 F.3d 523, 527 (D.C. Cir. 2004). The All Writs Act provides that the federal courts "may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. § 1651(a) (emphasis added). This statutory language makes clear that the authority to issue writs is confined to the issuance of process "in aid of" jurisdiction that is created by some other source and not otherwise enlarged by the Act. *In re Tennant*, 359 F.3d at 527.

5. No *Bivens* jurisdiction exists.

True Health seeks to bring an action against Defendants under *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971). However, this purported basis for jurisdiction fails as Defendants are clearly protected by sovereign immunity. The Fifth Circuit specifically addressed the issue sovereign immunity of HHS (then HEW) and its employees, in *Peterson v. Weinberger*, 508 F.2d 45 (5th Cir. 1975). The court found that individual government employees were shielded by immunity, given the absence of evidence that they acted outside of their line of duty or the scope of their employment in carrying out their official responsibilities. *Peterson*, 508 F.2d at 50–51.

Furthermore, federal officials are immune from suit unless their actions are *ultra vires* to their official responsibilities. *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949). The *ultra vires* exception to sovereign immunity provides that "where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions," or "*ultra vires* his authority," and thus not protected by sovereign

immunity. *Id.* However, to fall within the *ultra vires* exception to sovereign or governmental immunity, a plaintiff must "do more than simply allege that the actions of the officer are illegal or unauthorized." *Danos v. Jones,* 652 F.3d 577, 583 (5th Cir. 2011). Rather, the complaint must allege facts sufficient to establish that the officer was acting "without any authority whatever," or without any "colorable basis for the exercise of authority." *Id.* (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 n.11, 104 S. Ct. 900, 79 L. Ed. 2d 67 (1984). True Health failed to assert that Defendants acted outside of their official capacities. Therefore, jurisdiction does not exist.

B. True Health has failed to state a claim for which relief may be granted.

If the Court finds that it has jurisdiction over all or some of True Health's claims, Defendants alternatively argue that the Plaintiff has failed to state a claim for relief. Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Bell Atlantic Corp.*, 550 U.S. at 556); *see also Bell Atlantic Corp.*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level[.]"). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'shown'—'that the pleader is entitled to relief.'" *Ashcroft*, 556 U.S. at 679 (alteration omitted) (quoting Rule 8(a)(2)). Furthermore, under Rule 8(a)(2), a pleading must contain "a short and plain statement of the

claim showing that the pleader is entitled to relief." Although "the pleading standard Rule 8 announces does not require 'detailed factual allegations,'" it demands more than "'labels and conclusions.'" *Ashcroft*, 556 U.S. at 678 (quoting *Bell Atlantic Corp.*, 550 U.S. at 555). And "a formulaic recitation of the elements of a cause of action will not do." *Id.* (quoting *Bell Atlantic Corp.*, 550 U.S. at 555).

Under this standard, True Health fails to state a claim for relief. True Health does not dispute the Defendants' authority to suspend payments when they have a credible allegation of fraud. *See* Compl. (Doc. #2) at ¶25. Nor does True Health dispute that Defendants can continue a fraud-based payment suspension while an investigation into the potentially fraudulent activity continues. *See id.*, ¶28-29. Rather, True Health's request for the extraordinary remedy[6] preventing the Secretary from exercising the lawful right to protect the Medicare Trust Fund from fraud is predicated on the payment suspension reducing the amount paid to the provider suspected of fraud. *See id.*, ¶¶48-50.

In Counts I and II of its complaint, True Health asserts that "True Health's Medicare reimbursement for services performed, and continued participation in the Medicare program constitute valuable property rights within the meaning of the Fifth and Fourteenth Amendments to the United States Constitution." *Id.*, ¶¶65, 80. However, "[a] property interest must be secured by statute, legal rule or through a mutually explicit understanding between government and individual." *Sahara Health Care v. Azar*, 349 F. Supp. 3d 555, 571 (S.D. Tex. 2019). As

[6] "The power to grant injunctive relief should be exercised sparingly and with great caution, and only where the reason and necessity therefore are clearly established." *See Park View Heights Corp. v. City of Black Jack*, 454 F. Supp. 1223, 1227 (E.D. Mo. 1978). A plaintiff seeking an injunction must show: (1) a "substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of the injunction will not disserve the public interest." *Janvey v. Alguire*, 647 F.3d 585, 595 (5th Cir. 2011) (*quoting Byrum v. Landreth*, 566 F.3d 442, 445 (5th Cir. 2009)).

the Fifth Circuit explained when examining a Medicaid case with a similar issue, "[f]ederal law does not prohibit these payment holds . . . **[t]he statutory scheme does not give [the Medicaid medical supply provider] a property interest in its present reimbursement claims while past claims are under investigation for fraud."** *Pers. Care Prod., Inc. v. Hawkins*, 635 F.3d 155, 159 (5th Cir. 2011) (emphasis added). Likewise, the Fifth Circuit also found that Medicare suppliers do not have a property interest in participating in the Medicare program. *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("We agree with our four other sister circuits that have determined participation in the federal Medicare reimbursement program is not a property interest."). Since True Health has not identified a protected property interest, its procedural and substantive due process claims must fail.

In Count III, True Health asserts that Defendants violated the Administrative Procedures Act (APA) when they "acted in a manner that is "contrary to constitutional right" by suspending True Health's Medicare payments in violation of the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution." But, since True Health cannot establish a procedural or substantive due process claim, it likewise cannot establish a claim that Defendants violated the APA.

In Count IV, True Health alleges that it is entitled to writ of mandamus requiring Defendants to "(i) terminate their unlawful suspensions of Medicare payments to True Health until such time as an overpayment decision is issued and due process provided; (ii) immediately release the suspended funds being held in escrow by Defendants; and (iii) implement a full, speedy, and adequate administrative review process if Defendants intend to recoup or withhold any of True Health's Medicare payments in the future." Compl. (Doc. #2) at ¶107. But, as explained earlier, True Health has not established that it has ever had a clear right to receive the

relief that it seeks or that Defendants have a clear duty to provide such relief. Therefore, True Health's claim must fail.

In Count V, True Health asserts that "Defendants have acted beyond the scope of applicable laws and regulations in imposing a second Medicare payment suspension on True Health while the original suspension remains in place where the second suspension is based on the very same claims that were reviewed as part of the ongoing, original suspension." Compl. (Doc. #2) at ¶58. However, other than its bald assertion of harm, True Health has not provided a basis for a declaratory judgment against Defendants. Indeed, Medicare regulations allow Defendants to suspend payments when they receive "a credible allegation of fraud against a provider or supplier." 42 C.F.R. § 405.371(a)(2). Those regulations do not limit Defendants from suspending Medicare payments if a supplier continues to defraud the Program or finds new ways to do so. *See id.* Thus, Plaintiff has failed to state a claim.

C. True Health is not entitled to injunctive relief.

True Health, as the party seeking injunctive relief, must establish four requirements in this Circuit. Specifically, True Health must show (1) a substantial likelihood that it will prevail on the merits; (2) a substantial threat that irreparable injury will result if the injunction is not granted; (3) the threatened injury outweighs the threatened harm to Defendants; and (4) granting the preliminary injunction will not disserve the public interest. *Canal Auth. of State of Fla. v. Callaway*, 489 F.2d 567, 572 (5th Cir. 1974).

This discretionary and extraordinary remedy should be granted only if a plaintiff has clearly carried the burden of persuasion on all four *Callaway* requirements. *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985). In making such a showing, the movant bears a heavy burden particularly when, for example, the balance tips in defendant's

or the public's favor with respect to likely injury if the injunctive relief were granted to the moving party. Indeed, the decision to grant injunctive relief is to be treated as the exception rather than the rule. *Cherokee Pump & Equip. Inc. v. Aurora Pump*, 38 F.3d 246, 249 (5th Cir. 1994).

1. True Health cannot show substantial likelihood of success on the merits.

True Health cannot show that there exists a substantial likelihood of success on the merits of the claims it has asserted in this action. As outlined above, this Court does not have subject-matter jurisdiction to review True Health's claims because True Health has failed to identify a statutory basis for any of its claims. True Health's claims arise under the Medicare Act, and consequently, they may not be considered by this Court until True Health has administratively channeled its claims and received a final decision of the Secretary under 42 U.S.C. §§ 1395ff and 405(g).

Not only do True Health's claims for Medicare payments ("substantive claims") arise under the Medicare Act, so too does True Health's due process claim because it is inextricably intertwined with the relevant substantive claims. *Heckler*, 466 U.S. at 614; *Affiliated Prof'l Home Health Care Agency*, 164 F.3d at 282. That True Health's due process claim is inextricably intertwined with its claims challenging the Secretary's suspension of Medicare payments is self-evident on the face of True Health's Complaint. A determination of its due process claims would necessarily require this Court to delve into the propriety of the Secretary's determination to suspend Medicare payments to True Health. This Court would thus have to analyze the statutory and regulatory scheme provided under the Medicare Act regarding those matters. *Id.* Moreover, that likely also would require this Court to delve into the Department of Justice's investigation of True Health, including of the pending *qui tam* action filed in the

Sherman Division.

Even if this Court were to find that it has jurisdiction to determine one or more of True Health's claims, True Health has nevertheless failed to demonstrate a substantial likelihood of success on the merits. Here, the Secretary's suspension of Medicare payments action is based on credible allegations of fraud. Therefore, pursuant to the Secretary's regulations at 42 C.F.R. § 405.370 *et seq*., the Secretary was duly authorized to suspend payments to True Health. The Secretary's decision to suspend is unappealable. 42 C.F.R § 405.375(c).

Suspension of payments have been upheld where there has been concern about billing irregularities, *Friedman & Assocs. v. Pa. Blue Shield*, 836 F. Supp. 263 (E.D. Pa. 1993), or where overpayments are merely "suspected." *Arecibo Med. Hospice Care v. Shalala*, No. CIV. 94-1802(PG), 1994 WL 448678 (D.P.R. Aug. 18, 1994); *see also In re In re St. Johns Home Health Agency, Inc.*, 173 B.R. 238, 242–46 (Bankr. S.D. Fla. 1994), *Integrated Generics, Inc. v. Bowen*, 678 F. Supp. 1004, 1007 (E.D.N.Y. 1988).

A suspension of payment is a tool that allows Defendants to protect the Medicare Trust Fund from problematic providers. During the withholding, "[t]he claims continue to be processed and allowable amounts are credited to the provider's account," but payment is not made. *Neurological Assocs.-H. Hooshmand, M.D., P.A. v. Bowen*, 658 F. Supp. 468, 471 (S.D. Fla. 1987). "The government is afforded the protection of determining whether past overpayments have been made and can prevent future losses by temporarily withholding payments, while still processing all claims." *Id.* The preamble to the regulations states that "[t]he purpose of suspending payment is to verify whether, and how much, payment was actually due to the provider for past claims and to ensure that, if a provider or supplier was overpaid, sufficient funds are available to recover the overpayment. These actions are clearly to protect the

Medicare Trust Funds from loss." Medicare Program; Changes Concerning Suspension of Medicare Payments, 61 Fed. Reg. 63740, 63742-43 (Dec. 2, 1996).

It bears noting that, contrary to True Health's colorful arguments, the United States' diligent investigation into True Health's fraud schemes—and the concomitant halt on the payment of taxpayer money to such an entity—is a far cry from the dystopian and oppressively bureaucratic regimes depicted in the works of Franz Kafka. *See* Compl. (Doc. 1) at ¶9. To the contrary, countless government employees have worked tirelessly for years to identify the extent of True Health's unlawful schemes, which surely is preferred over inaction in the face of systematic and pervasive fraud perpetrated on the Medicare Program. Affirmative steps to prevent the abuse of taxpayer funds and to ensure repayment for prior harm inflicted represents the epitome of good and responsible government.

The courts have sustained the Secretary's suspension authority in circumstances similar to those present here. In *Clarinda Home Health v. Shalala*, 100 F.3d 526 (8th Cir. 1996), a home health agency's Medicare payments were suspended. Finding that the provider had no viable constitutional claim, the Eighth Circuit, citing *Peterson v. Weinberger*, 508 F.2d at 45, held that "the withholding is nothing more than a temporary measure necessary to maintain the status quo while the necessary facts are gathered and evaluated." *Clarinda Home Health*, 100 F.3d at 530. In *Cplace Springhill SNF, LLC v. Burwell*, No. CIV.A. 14-3139, 2015 WL 1849499, at *5 (W.D. La. Apr. 22, 2015), the court cited to *Shalala*, 529 U.S. at 12–13 in holding that the granting of jurisdiction to hear the plaintiff's challenge to the suspension of its Medicare payments "would result in precisely the type of interference that the binding case law cautions against." In *Silverado Hospice, Inc. v. Harden*, No. SACV 17-2018, WL 6185966 (Feb. 2, 2018), the court found that it did not have jurisdiction because the plaintiff did not exhaust its administrative

rights and any procedural irregularities can be addressed by the court after exhaustion. In *MedPro Health Providers, LLC v. Hargan*, No. 17 C 1568, 2017 WL 4699239, at *5 (N.D. Ill. Oct. 19, 2017), the court found that exhaustion would not be futile because plaintiff could raise alleged violation of regulations during administrative appeal of overpayment decisions. And, in *Midwest Family Clinic, Inc. v. Shalala*, 998 F. Supp. 763 (E.D. Mich. 1998), the court rejected arguments that the suspension action violated plaintiff's due process rights.

In addition, True Health's corporate business interest is significantly less compelling than an individual's interest in receiving, for example, social security benefits. The Medicare program is voluntary and providers such as True Health participate with no guarantee of solvency. *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719 (6th Cir. 1991). The Medicare program was enacted to provide health care for the poor and aged—not to subsidize or otherwise benefit healthcare providers. *Cervoni v. Sec'y of Health, Ed. & Welfare*, 581 F.2d 1010 (1st Cir. 1978); *see also Green v. Cashman*, 605 F.2d 945 (6th Cir. 1979). A provider's interest in the Medicare program is "incidental to the purpose and design of the [Medicare] program." *Northlake Cmty. Hosp. v. United States*, 654 F.2d 1234 (7th Cir. 1981). Moreover, a provider's interest in participating in the Medicare program is subject to a statutory and regulatory scheme to which providers agree when they sign Medicare applications and agreements.

2. Plaintiff has not shown irreparable harm.

True Health has also failed to show irreparable harm if injunctive relief is not granted. True Health's contention that it will be forced out of business if the suspension continues is unsubstantiated. As an initial matter, the Declaration of Christian Richards offered by True Health as evidence of irreparable harm is insufficient on its face. First, Richards admits that

Medicare payments only constitute approximately 30% of True Health's revenue. [Richards Decl. at ¶4.]. In addition, Richards admits only that "True Health will be *nearly* out of cash on or before July 8, 2019." *Id.* at ¶6 (emphasis added). It is unclear what exactly this means. And even more unclear is why True Health apparently cannot avoid bankruptcy when 70% of its business is unaffected by the active suspension.

Nonetheless, True Health has complained about imminent financial ruin for the past seventeen months without ceasing operations, freezing executive distributions, or slowing recruitment to its legal team. *Id.* at ¶¶21-29]. At best, True Health's claims are undermined by its continued financial dealings. At worst, any financial hardship was self-manufactured by a dubious recapitalization which stripped True Health of its ability to satisfy any legitimate obligations while simultaneously enriching company executives and shareholders. *Id.* at ¶¶28-29]. The approximately $20 million currently held in escrow pursuant to the 2017 payment suspension, which True Health blames for its insolvency, pales in comparison to the approximately $130 million True Health took out of the company and distributed to its executives and investors in 2017.

Either way, True Health's contentions will not support injunctive relief because such economic threat does not constitute irreparable harm. *See generally, Sampson v. Murray*, 415 U.S. 61 (1974) (loss of income is not an irreparable injury); *Physician Hospitals of America*, 691 F.3d at 655 *of Am. v. Sebelius*, 691 F.3d 649, 655 (5th Cir. 2012) ("severe economic impracticability" was not enough for a plaintiff to allege that it cannot channel its claims through the agency); *KMW Int'l v. Chase Manhattan Bank, N.A.*, 606 F.2d 10, 15 (2d Cir. 1979) (because damages were only financial, preliminary injunction should not have issued); *Cf. Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 602 F.2d 150, 153–154

(8th Cir. 1979) (participation in Medicaid by a nursing home provider of services is voluntary, and the provider's need is "incidental" to the government program); *Thorbus v. Bowen*, 848 F.2d 901, 904 (8th Cir. 1988) (loss of 60% of gross income due to loss of Medicare and Medicaid not irreparable). Moreover, the threat of bankruptcy does not satisfy the required showing of irreparable injury. *V.N.A. of Greater Tift Cty., Inc. v. Heckler*, 711 F.2d 1020 (11th Cir. 1983). The Fifth Circuit recently held in *Family Rehab.* that the "combined threats of going out of business and disruption to Medicare patients are sufficient for irreparable injury." *Family Rehab. Inc.*, 886 F.3d at 504. However, even if True Health's evidence were sufficient (it is not) to establish that a suspension of payments associated with 30% of its business were enough to put it out of business, Family Rehab's allegations bear no semblance to True Health's. Family Rehab alleged that "[n]early all of its revenue—between 88 and 94 percent—comes from Medicare-reimbursable services." *Family Rehab., Inc.*, 886 F.3d at 499. Also, Family Rehab provided home healthcare services to, presumably, an established patient base. True Health operates in the heavily-saturated field of diagnostic testing, including blood labs. The threat to disrupting Medicare patients' access to diagnostic testing is virtually non-existent.

Furthermore, once available administrative remedies are exhausted, the reviewing court, if jurisdiction is otherwise proper, has full power to vindicate any rights grounded in regulation or statute. The availability of judicial review at the legally and procedurally appropriate time means any harm suffered by True Health would not rise to the level of "irreparable harm." *Sampson*, 415 U.S. at 88.

3. The balance of hardships does not tip in True Health's favor.

In contrast to True Health's pecuniary interest, Defendants' interest in preserving the integrity of the Medicare program is paramount to the functioning of a viable healthcare program

in this country. Enjoining Defendants from their lawful responsibilities related to administering the Medicare program serves only to disrupt the congressionally-mandated process for review of Medicare disputes. *Physician Hospitals of America*, 691 F.3d at 657 (a provider's claim that the administrative review process would cause it to incur extraordinary expenses did not except it from the administrative channeling requirement.); *V.N.A. of Greater Tift County, Inc.*, 711 F.2d at 1033–35 (noting that the district court holding a full hearing on the merits "seriously disrupts the congressionally-mandated process."). Moreover, the kinds of financial hardships True Health claims "must have been contemplated by Congress and are the necessary result of the statutory scheme under the Medicare Act when a provider depends on Medicare payments as its primary source of income." *Indeplus Group of Companies, Inc.*, 2010 WL 1372488, at *3.

The Secretary has a strong interest in protecting the Medicare program from financial loss—True Health does not argue otherwise. This interest would be undermined severely if the Secretary was forced to cease withholding funds before completing investigations, and innocent taxpayers would bear the cost. *See Midwest Family Clinic, Inc.*, 998 F. Supp. 763.

4. The public interest does not favor injunctive relief.

For the reasons stated immediately above, the issuance of the injunction sought by True Health would strongly disserve the public interest. The Secretary, has an interest in ensuring that the Medicare program is operated in the manner specified by Congress and is protected from fraud and abuse. The public interest cannot be served when companies such as True Health—that have submitted fraudulent claims to Medicare—are allowed unfettered access to the Medicare Trust Fund while Defendants and their law enforcement partners investigate the fraudulent claims. Likewise, the public interest is not served when these entities are allowed to circumvent the administrative review process—as well as the explicit directives of Congress—by

compelling Medicare payments without fully exhausting their administrative remedies. Exhaustion is generally required as a matter of preventing interference with agency processes so that the agency may function efficiently and have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record that is adequate for judicial review. *Weinberger*, 422 U.S. at 765; *see also Good Samaritan Med. Ctr. v. Sec'y of Health & Human Servs.*, 776 F.2d 594, 599 (6th Cir. 1985). In short, judicial interference at this stage of the Executive Branch's investigation would represent a separation of powers concern, particularly where subject-matter jurisdiction is wholly lacking.

D. This action should not be sealed.

True Health asks the Court to seal this case. True Health's lead argument for sealing this action is that its customers will likely not want to do business with True Health if they were aware of the extent of the legal exposure it faces to the United States. *See* Mot. to Seal (Doc. #1) at p.1. Counsel for the United States is duty-bound to "protect the societal interest in open proceedings." 28 C.F.R. § 50.9. Defendants do not wish to litigate these issues in secret and stridently object to the sealing of these proceedings.

True Health also argues that sealing is necessary as its "Complaint discusses . . . a qui tam lawsuit[.]" The seal in *qui tam* suits protects the United States and its investigation. *See* 31 U.S.C. § 3730(b)(3). As is clear from True Health referencing the case in its Motion to Seal, the United States has already obtained a partial lift of the seal from Judge Mazzant in the Sherman Division and has disclosed the existence of the case to True Health. Accordingly, the United States has no objection to the existence of the case against True Health being disclosed publicly at this time. However, the United States requests that any information about other defendants in the *qui tam* be redacted in this action.

To be sure, the related *qui tam* case is pending before Judge Mazzant, who has previously ruled on related sealing issues. Accordingly, should this matter not be dismissed for want of subject-matter jurisdiction, the United States contends that this action should be litigated before the same judge assigned to hear the *qui tam* lawsuit. The United States foresees potentially competing rulings if these actions are litigated before separate judges. For instance, any order requiring Defendants here to release any escrowed funds would likely require the United States to seek a writ of sequestration of those funds in the *qui tam* suit to prevent dissipation of assets that can be used to fulfill or partially fulfill a judgment against True Health.

VI. CONCLUSION

The regulations authorizing the temporary withholding of funds have been repeatedly upheld as lawful and are specifically designed to protect the integrity of the Medicare Trust Fund. Defendants have made a final determination as to the amount of the overpayment determination related to the first payment suspension in the instant case. True Health may now invoke its appeal rights with respect to the overpayment determination related first payment suspension under the Medicare Act. However, until True Health exhausts its administrative rights regarding the overpayment determination, True Health is not entitled to judicial review. If True Health ultimately does experience exhaustion-related delays, there is a process in place that will allow True Health to expedite its administrative appeal.

Defendants respectfully ask the Court to follow the settled case law supporting Defendants' position that True Health's Complaint be dismissed for lack of subject-matter jurisdiction. Accordingly, it is respectfully submitted that the Court should refrain from issuing injunctive relief and should defer to the comprehensive Medicare process mandated by Congress and administered by the Secretary.

Respectfully submitted,

JOSEPH D. BROWN
United States Attorney

/s/ Joshua M. Russ
JOSHUA M. RUSS
Assistant U.S. Attorney
Lead Attorney
Eastern District of Texas
101 East Park Blvd., Suite 500
Plano, Texas 75074
E-mail: Josh.M.Russ@usdoj.gov
(972) 509-1201
(972) 509-1209 (fax)
Texas State Bar # 24074990

JAMES GILLINGHAM
Assistant U.S. Attorney
Eastern District of Texas
110 N. College Street; Suite 700
Tyler, Texas 75702
E-mail: James.Gillingham@usdoj.gov
(903) 590-1400
(903) 590-1436 (fax)
Texas State Bar # 24065295

ATTORNEYS FOR THE
UNITED STATES OF AMERICA

OF COUNSEL:

Robert P. Charrow
General Counsel

Mervin Turner
Chief Counsel

E. Dante Anderson
Coordinating Attorney
United States Department of Health and Human Services
Office of the General Counsel
Region VI
1301 Young Street, Suite 1138
Dallas, Texas 75202

CERTIFICATE OF SERVICE

I hereby certify on this 5th of July, 2019, I caused copies of the Defendants' Motion to Dismiss and Combined Response to Plaintiff's Motion For Temporary Restraining Order and Motion to Seal Case, exhibits, and proposed order, to be served by electronic mail on:

J. Thad Heartfield (thad@heartfieldlawfirm.com)
The Heartfield Law Firm
2915 Dowlen Road
Beaumont, Texas 77706

Michael S. Nadel (mnadel@mwe.com)
Rebecca C. Martin (rcmartin@mwe.com)
Paul M. Thompson (pthompson@mwe.com)
Michael B. Kimberly (mkimberly@mwe.com)
McDermott Will & Emery LLP
500 N. Capitol Street, N.W.
Washington, D.C. 20001

/s/ *James Gillingham*
JAMES GILLINGHAM